

## **LEADER URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet**

### **Cardinal Health**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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## **DRUG FACTS**

### **Active Ingredient**

Phenazopyridine Hydrochloride 95 mg

### **Purpose**

Urinary Tract Analgesic

### **Uses**

fast relief from urinary pain, burning, urgency and frequency associated with urinary tract infections.

### **Warning**

Do not exceed recommended dosage

### **Ask Doctor before use if you have**

- kidney disease
- allergies to foods, preservatives or dyes
- had a hypersensitive reaction to Phenazopyridine

### **When using this product**

- When using this product stomach upset may occur, taking this product with or after meals may reduce stomach upset
- your urine will become reddish-orange in color. This is not harmful, but care should be taken to avoid staining clothing or other items.

### **Stop use and ask a doctor if**

- your symptoms last for more than 2 days
- you suspect you are having an adverse reaction to the medication

**If pregnant or breast feeding**

ask a health professional before use.

**Keep out of the reach of children**

in case of an overdose, get medical help or contact a Poison Control Center right away.

**Directions**

■ Adults and children 12 and over: take 2 tablets 3 times daily with a full glass of water, with or after meals as needed

■ **Children under 12:** consult a doctor

■ **Do not use for more than 2 days (12 tablets) without consulting a doctor**

**Inactive Ingredients**

lactose, magnesium silicate, magnesium stearate, microcrystalline

cellulose, pharmaceutical glaze, and sodium starch glycolate. May also contain: corn starch,

croscarmellose sodium, polyvinylpyrrolidone, pregelatinized starch and silicon dioxide.



## LEADER URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0243
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENAZOPYRIDINE HYDROCHLORIDE</b> (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	95 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>SHELLAC</b> (UNII: 46N107B710)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	

**SODIUM STARCH GLYCOLATE TYPE A CORN** (UNII: AG9B65PV6B)

**LACTOSE** (UNII: J2B2A4N98G)

**MAGNESIUM SILICATE** (UNII: 9B9691B2N9)

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	P95
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0243-1	1 in 1 CARTON	02/01/2017	
1		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2013	

**Labeler** - Cardinal Health (063997360)

**Registrant** - Reese Pharmaceutical Co (004172052)